

### **REMARKS**

By this submission previously pending claims 27, 29, 31 and 32 are amended and new claims 35-39 are submitted for introduction. No new matter is introduced by the now submitted amendments or the new claims.

It is requested in view of the submitted amendments and the following discussions that all rejections reported in the outstanding Office action be reconsidered and not repeated in any further action issued for this application.

#### **Claim Rejections – 35 USC §112**

Rejections under 35 USC §112, second paragraph, are reported in the Office action as being directed to claims 27-29, 31 and 32 for being indefinite in failing to particularly point out and distinctly claim subject matter that is regarded as the invention. These reported rejections are believed to be overcome in view of now submitted amendments and the following discussions.

With respect to these rejections, it is reported that both claims 27 and 31 recite “said cutting member” at line 4, but that apparent antecedent basis is a “cutting device.” The subject claims have been amended in all relevant instances to recite “said...cutting device.” As such it is submitted that all 35 USC §112, second paragraph, rejections are overcome.

#### **Claims Rejections - 35 USC §103**

Rejections under 35 USC §103(a) are reported in the Office action as being directed to claims 27-29, 31 and 32 as being unpatentable over US Patent No. 5,209,749 (hereinafter “Buelna”). These reported rejections are believed to be overcome in view of now submitted amendments and the following discussions.

Claims 27 and 31 of the reported rejected claims are independent, and all other reported rejected claims are dependent from one or the other of these two independent claims. Attention now will be directed to these two independent claims, because if an independent claim recites

allowable subject matter then all claims dependent from that independent claim also recite allowable subject matter.<sup>1</sup>

Turning to claims 27 and 31, it is seen that they both substantively at least recite:

A method for determining length of exposure of a tissue cutting device from a distal portion of a lumen..., which comprises:  
providing said tissue cutting device with a plurality of radiopaque indicia located...along a length of said tissue cutting device...;  
deploying said tissue cutting device to be exposed from said distal portion of said lumen; and  
radiographically determining the length of said tissue cutting device as deployed from said distal portion of said lumen.

So providing “radiopaque indicia” is recited for “...determining the length of said tissue cutting device...from said distal portion of said lumen.” In contradiction Buelna discloses use of “radiopaque marker pattern[s]” to visualize “both the angular orientation and the longitudinal position of cutting within the body vessel, orifice, or conduit...” (col. 2, lines 25-31) Not disclosed or suggested by Buelna is determining a length that any cutting device is extended from a distal portion of a lumen. Such failure on the part of Buelna can not be overcome because Buelna “teaches [marking] the plurality of indicia on the catheter,” as is stated in the action at page 3, section 5. This failure on the part of Buelna is asserted in the action as not being fatal because it is asserted that “it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the plurality of indicia on the cutting member instead of the catheter since it has been held that a mere reversal of the essential working parts of a device involves only routin[e] skill in the art. *In re Gazda*, 219 F.2d 449, 104 USPQ [400] (CCPA 1955).” Here, as clarified by now submitted amendments, the pending independent claims 27 and 31 both recite a method for “deploying said tissue cutting device to be exposed from said distal portion of said lumen; and radiologically determining the length of said tissue cutting device as deployed [or which is exposed] from said distal portion of said lumen.” Buelna fails to disclose or suggest accomplishment of such process steps because Buelna described structure are

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<sup>1</sup> “Dependent claims are nonobvious under 103 if the independent claims from which they depend are nonobvious.” (Citations omitted, *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988))

incapable of accomplishing such process steps. Instead, Buelna discloses that a “cutting element 18, which is generally itself radiopaque, is supported by the cutting element support 12” (col. 2, lines 63-65), and that “[a] radiopaque marker pattern is carried by the support, the pattern being such that by fluoroscopic viewing of the pattern a user can determine the orientation of the element about the axis.” (col. 2, lines 4-7) Thus, Buelna discloses marking a cutting element support, not a tissue cutting device. Therefore, Buelna fails to disclose or in any way suggest a method for determining exposure of a tissue cutting device from a distal portion of a lumen by radiologically determining a length away from a lumen. As such, it would not have been obvious to anyone of ordinary skill in the art at the time the invention was made to modify the Buelna structure, because the disclosed uses of the Buelna structures are distinct from and in contradiction to the now pending method steps. At least in these contexts Buelna teaches away from the recited subject matter in the pending claims.

It is submitted that the now amended claims and above discussions overcome all reported 35 USC § 103 rejections.

#### **New claims**


Now submitted new claims 35-39 are drafted to mirror in apparatus format now amended method claims discussed above. As such, it is submitted both that these new claims are within recitations for all prior claims elected for examination and that they recite allowable subject matter over all references of record.

**CONCLUSION**

It is believed that all pending and new claims are in condition for allowance and a notice of the same is requested. Should the Examiner have any questions, requests or suggestions, he is invited to contact the undersigned attorney at the telephone number set out below.

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Respectfully submitted,

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